Case Study Review of Chronic Pain Patients

A Law Enforcement Perspective

The Last Year in Prescription Drug Abuse…

- **Zohydro**
  - First hydrocodone-only opioid narcotic that is reportedly five to ten times more potent than traditional hydrocodone products, and has no abuse-deterrent properties.
  - Came to market in March 2014
  - Proposal for Tamper Resistant Zohydro:
    - It has been reported recently that Zogenix (maker of Zohydro) has submitted a supplemental application to the FDA for a new form of Zohydro extended-release capsules that make it difficult to snort or inject.
    - If approved, which the company expects to occur in the first quarter of 2015, the drug maker would replace the current version of Zohydro in the second quarter of 2015.

- **DEA Reschedule of Drugs:**
  - Tramadol (effective August 18, 2014) placed tramadol into a Schedule IV
    - Applies to all tramadol salts, isomers, and salts of isomers.
  - Hydrocodone (effective Oct. 6, 2014) reschedules hydrocodone combination products from schedule III to schedule II
- **Indiana Medical Licensing Board passed final rule (will cover later)**

Legal Materials
Prescription Drug Abuse

- Possible Charges
- Case Law
- Standards of Practice
- Other medical professionals
- Indiana Medical Board's Prescribing Rules

Possible Charges

- NOTE:
- New version of criminal sections are effective 7-1-2014
- Citations given in this presentation are currently accurate and will lead you to the citation effective after 7-1-2014
- Felony classification should be based on the Date of Offense
- The main change deals with the classification of felony for the offense

Possible charges continued:

- Drug Charges:
  - I.C. 35-48-4-2 Dealing a Schedule I, II, or III controlled substance

    I.C. 35-48-4-3 Dealing a Schedule IV controlled substance

    I.C. 35-48-4-4 Dealing a schedule V controlled substance

- *A person who:*
  - *Knowingly or intentionally – manufactures, delivers, or finances the delivery of a controlled substance*
  - *Possesses with the intent to – manufacture, finance the manufacture of, deliver, or finance the delivery of a controlled substance*
  - *Class B felony*
  - *The offense is a Class A felony if:*
    - *Delivered or finance the delivery of substance to person under 18 years old*
    - *OR delivery, or finances the delivery, occurred on a*
      - *School bus*
      - *Or within 1,000 feet of school property, public park, family housing complex, or youth program*

- Drug Charges
  - **IC § 35-48-4-14(b) Offenses relating to registration labeling and prescription forms**
    - *A person who knowingly or intentionally acquires possession of a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, alteration of a prescription . . . Commits a Class D felony.*
    - *A person who duplicates, reproduces, or prints any prescription pads or forms without the prior written consent of a practitioner commits a Class D felony.*
  - **IC § 35-48-4-13 Visiting or maintaining a common nuisance**
    - *A person who knowingly or intentionally visits a building, structure, vehicle, or other place that is used by any person to unlawfully use a controlled substance commits visiting a common nuisance.*

IC § 35-43-5-7.1 Medicaid Fraud

Note :

- IC § 35-43-5-7.1(a)(1) was found unconstitutionally vague as applied in *Healthscript, Inc. v. State of Indiana*, 770 N.E.2d 810 (Ind. 2002).
- * We recommend that you file Medicaid Fraud charges under IC § 35-43-5-7.1(a)(1) – (5) or IC § 35-43-5-7.1(b) if fair market value of the loss to Medicaid exceeds $100,000.

Case Law (Indiana Cases)

- **Tobias v. State, 479 N.E.2d 508:** Pharmacist
  - *Registered pharmacist could be tried and convicted of dealing pursuant to IC 35-48-4-1 (1982 Ed.) for delivering controlled substances in the amount of three grams or more, as there is no language in statute prohibiting charging a pharmacist and controlled substances were not dispensed as required by pharmacist's registration or valid prescription.*

- **Alarcon v. State, 573 N.E.2d 477 (Ind.Ct.App.1991): Physician**
  - Reasoning:
    - *Agreed with reasoning in U.S. Supreme Court in Moore*
    - *Agreed with Indiana Supreme Court in Tobias*
  - Holding:
    - *Indiana "Dealing" statutes apply to licensed physicians who write prescriptions for scheduled drugs*
    - *A physician that has issued prescriptions without legitimate medical purpose or outside the usual course of his professional practice was sufficiently supported by evidence in narcotics prosecution,*
      - *Including evidence that physician had written prescriptions without physical examination or questioning or with only cursory examination or questioning, that he postdated prescription when date of issuance was too close in time to prior prescription, and that he had occasionally refused to issue requested prescriptions, expressing concerns about police surveillance.*

Case Law (Federal cases)

- **U.S. v. Rosenberg, 515 F.2d 190 (1975)**
  - *The phrase "in the course of professional practice" within the Act was not so vague as to deny due process*
  - *The use of doctor's medical files against him did not violate his right against self-incrimination*

- **U.S. v. Feingold, 454 F.3d 1001 (9th Cir. 2006)**
  - *Lack of Training Defense: claimed that he was an incompetent doctor who was honestly trying to help his patients manage pain, didn't know that they were abusing the drugs due to his lack of training about the use of opioids, and never intended to flout professional protocol. – Jury rejected this argument.*

- **U.S. v. Katz, 445 F.2d 1023 (8th Cir. 2006)**
  - *Rule: "Willful Blindness Instruction" – appropriate when the defendant asserts lack of guilty knowledge, but the evidence supports an inference of deliberate ignorance. Ignorance is deliberate if the defendant presented with fact that put her on notice that criminal activity was particularly likely and yet she intentionally failed to investigate the facts.*

Standards of Practice (Owner)

- **Owner of a Practice (even if a non-practitioner)**
  - Registration: An owner must have a CSR issued by the board (effective 1/1/2014) **(IC 35-48-3-3).**
  - Must ensure Reasonable procedures: to ensure all employees in the location dispenses controlled substances in a manner that complies with laws, rules, and regulations

Standards of Practice (Physician)

- **PHYSICIANS' LICENSES:**
  - Medical License with the Indiana State Medical Board
  - Controlled Substance Registration (CSR) with Indiana Pharmacy Board
    - Required for any person manufactures, distributes, or dispenses controlled substances within the state **(IC § 35-48-3-3).**
    - Dispensing CSRs expire when practitioner's medical license expires **(IC § 35-48-3-3).**
  - DEA Registration Number to prescribe controlled substances.

- **SUPERVISING OTHER PRESCRIBERS:**
  - Physician Assistants (PAs):
    - If a Physician supervises Physician Assistants (PAs), the Physician must have a supervising practice agreement with that PA. See requirements of practice agreement in the PA standards.
    - A physician may enter into a supervising agreement with more than two PAs but may not supervise more than two PAs at the same time. **(IC § 25-27.5-6-2)(844 IAC 2.2-2-2)**
  - Advanced Practice Nurses (APNs):
    - If a Physician collaborates with a Advanced Practice Nurse (APN), the Physician must have a practice agreement with that APN. See requirements of practice agreement in the APN standards.

Standards of Practice (Physician) continued:

- **SCHEDULE II CONTROLLED SUBSTANCES FOR WEIGHT LOSS:**
  - A physician shall not utilize, prescribe, order, dispense, supply, sell, or give an amphetamine, sympathomimetic amine drug or compound designated as a Schedule II controlled substance pursuant to the provisions of IC 35-8-2-6 to any person for purpose of weight reduction or for control in the treatment of obesity **(844 IAC 5-2-20).**

- **PRESCRIBING TO PERSONS NOT SEEN BY THE PHYSICIAN:**
  - A physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.

  - Except in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority practicing in accordance with standard care arrangements, as described in subsection (d), a physician shall not prescribe, dispense, or otherwise provide, or cause **(844 IAC 5-4-1).**

Standards of Practice (APN)

- **THE TERM APN INCLUDES:**
  - Nurse practitioners (NP),
  - Certified nurse-midwife, and
  - Clinical nurse specialist (CNS). **(848 IAC 3)**
- **LICENSES:**
  - Nursing License with Indiana Nursing Board
  - Controlled Substance Registration (CSR) with the Indiana Pharmacy Board; and
  - DEA Registration Number to prescribe controlled substances.
    - MUST prescribe under APN's separate DEA registration number.
- **PRESCRIPTIVE AUTHORITY:**
  - Can prescribe controlled substances if operating in collaboration with a licensed physician (MD) as evidenced by a practice agreement (**IC § 25-23-1-19.4**).
  - Can prescribe controlled substances: (**IC § 25-23-1-19.6**)
    - Within the scope of the APN's practice AND
    - The scope of the collaborating MD.

Standards of Practice (APN) continued:

- **PRACTICE AGREEMENT SHOULD INCLUDE: (848 IAC 5-1-1 (A)(7))**
  - Name, address, and phone number of APN and MD;
  - A list of all office locations that APN is authorized to prescribe;
  - All specialty and board certifications of APN and MD;
  - Special manner of collaboration of between APN and MD;
    - How they will work together;
    - Share practice trends and responsibilities;
    - Maintain geographic proximity; and
    - Provide coverage during absence, incapacity, infirmity, or emergency.
  - Limitations MD has placed on APN's prescriptive authority;
  - Time and manner of APN review by MD. Including:
    - APN must submit documentation of prescribing practices to MD within 7 days.
    - Documentation of prescribing practices shall include at least 5% random sampling of the charts & medications of prescribed patients
  - List of other practice agreements between APN and MD; AND
  - Duration of agreement between APN and MD.

Standards of Practice (PA)

- **LICENSES:**
  - Physician Assistant (PA) License with Physician's Assistant Committee
  - Controlled Substance Registration (CSR) with the Indiana Pharmacy Board; and
  - DEA Registration Number to prescribe controlled substances.
    - MUST prescribe under PA's separate DEA registration number.
- **PRESCRIPTIVE AUTHORITY:**
  - Must engage in a dependent practice with physician supervision **(IC § 25-27.5-5-2).**
  - May perform, under the supervision of the supervising physician, the duties and responsibilities that are delegated by the supervising physician that are within the supervising physicians scope of practice, including dispensing drugs and medical devices **(IC § 25-27.5-5-2).**

Standards of Practice (PA) continued:

- **SUPERVISORY AGREEMENT**
  - Requires a supervisory agreement with a supervising physician that must: **(IC § 25-27.5-5-2) (844 IAC 2.2-1.1-16)**
    - Be in writing
    - Include all tasks being delegated to PA by physician
    - Set forth supervisor plans for the PA, AND
    - Specify the name of the drug, drug classifications being delegated to PA, and the protocol the PA shall follow prescribing the drug.
    - Setting in which PA will be supervised.
    - Names, address, and phone number of PA and MD
  - Supervisory agreement is submitted and approved by the board **(IC § 25-27.5-5-2).**

Standards of Practice (PA) continued:

- **CONTINUOUS SUPERVISION (IC § 25-27.5-6-1)**
  - Does not require supervising physician to be physically present at the time and place the services are rendered
  - Supervising physician shall review all patient encounters not later than 72 hours after the PA has seen the patient; for the following percentage of charts:
    - 1st year of PA employment = 100% of patient charts
    - 2nd year of PA employment = 50% of patient charts
    - 3rd year of PA employment = 25% of patient charts
    - 1st year of PA's prescribing authority = 100% of patient records which obtained controlled substances by dispensing or prescription
- **PA PRESCRIBING STATUTES FOR CONTROLLED SUBSTANCES (3 VERSIONS)**
  - **Effective July 1, 2007 – July 1, 2011**
  - **Effective July 1, 2011 – July 1, 2013**
  - **Effective July 2, 2013 - Current**

Other Medical Professionals

- Medical Assistants (MAs), Registered Nurses (RNs), License Practical Nurses (LPNs), or Certified Nurse Aides (CNAs)
  - NO Prescribing or diagnosing abilities.

Standards of Practice

	Diagnose Patients	Need Collaborating Physician to Prescribe C.S.	Prescribe Schedule I	Prescribe Schedule II C.S.	Refill Schedule II C.S.	Prescribe III, IV, and V C.S.	Refill III, IV, and V C.S.	Prescribe C.S. for Weight Loss
Physician	✓	✗	✗	✓	✓	✓	✓	✓
Advance Practice Nurse (APN)	✓	✓	✗	✓	✓	✓	✓	✗
Physician Assistant								
7/1/2007 – 6/30/2011	✗	✓	✗	✗	✗	✓ (Cannot contain Oxycodone & only 7 day supply)	✗	✗
7/1/2011 – 6/30/2013	✗	✓	✗	✗	✗	✓ (1 time, 30 day supply)	✗	✗
7/1/2013 – Present	✗	✓	✗	✓ (30 day supply)	✓ (as authorized by MD)	✓ (30 day supply)	✓ (authorized by MD)	✗

The New Indiana Laws for Safer Opioid Use in Chronic Pain Management

- **A Physician Must…..**
  - Perform detailed history and physical
  - Review records from previous healthcare providers
  - Have the patient complete an objective pain assessment tool
  - Do a Risk Assessment, including both
    - Mental Health assessment – use validated tool
    - Risk of substance abuse assessment – use validated tool
  - Tailor a diagnosis & treatment plan with functional goals
  - When appropriate, use non-opioid options
  - Counsel women on neonatal abstinence syndrome
  - Consider urine drug monitoring to test for compliance and unexpected drug use based on an 18 point factor test

The New Indiana Laws for Safer Opioid Use in Chronic Pain Management

- A Physician Must.....
  - Query INSPECT
  - Meet with patient at least every four months
  - Sign a Treatment Agreement including...
    - Goals of treatment
    - Consent to drug monitoring / Permission to conduct random pill counts
    - Prescribing policies, including prohibition of sharing medications & requirement to take medications as prescribed
    - Information on pain medications prescribed by
    - other physicians
    - Reasons that opioid therapy may be changed or discontinued
  - If the patient's opioid dose reaches a morphine equivalent of 60 milligrams/day, face to face review of the treatment plan is required, including consideration of consultation and counseling of risk of therapy, including death

Types of Licenses

- There are four different licenses a physician can hold in the state of Indiana:
- State medical license
- DEA registration
- CSR (Controlled substance registration)
- Addiction treatment license “X”

State Medical

- State Medical:

- To practice medicine in the state of Indiana, EVERY physician must have this.

DEA Registration

- This license is issued by the DEA to physicians who choose to prescribe or dispense controlled substances
- It is not a mandatory license
- A physician may practice without a DEA registration
- Without this a physician can still prescribe blood pressure meds, antibiotics, etc.,

CSR
Controlled Substance Registration

- This license is issued by the state
- If a physician chooses to have a DEA license, they must have a CSR. IT IS NOT OPTIONAL!
- Easiest explanation: It is a state DEA license
- If a physician loses or surrenders their DEA license, their CSR also becomes invalid.

Federal Addiction Treatment

- Known as an “X” license – Data-waived
- Separate from a regular DEA license
- Affords a physician the opportunity to treat up to 100 patients (30 the first year)

Options Available for Dealing with Physicians

- Speaking with the physician
- Education
- Voluntary Surrenders
- Licensing Action
- Civil
- Criminal

Speaking with the Physician

- Controversial
- Have to ensure the physician is not under investigation: check with the DEA, ISP, MFU
- Need concrete evidence: Has Law Enforcement actually purchased medications from the patients receiving them or have these patients been arrested for offenses related to their prescriptions drugs

Education

- Many times physicians are not aware of what goes on in the streets with prescription medications
- Unaware of the medical combinations
- Unaware of street prices of prescription medications
- Need assistance setting up medical practices to ensure they can more effectively monitor their patients

Voluntary Surrenders

- Can be used by physicians who find themselves being bullied into writing prescriptions for controlled substances (elderly)
- Can be used if a physician is prescribing outside the scope of their field., ex. Podiatrist writing wife diet pills
- Can be used by a physician over-prescribing but not to the level of a criminal case
- Generally always requested when criminal charges are filed
- If a physician refuses and DEA believes action is warranted, DEA will file a Show Cause Hearing

Licensing Action

- Taken when administrative rules are broken or criminal activity occurs
- Occur independently of each other; however, the licensing can have an impact on the criminal
- EX. Prosecutor decides if their license was sanctioned, he/she might not file; dismiss or agree to licensing/treatment in lieu of conviction

Civil

- Generally pursued by DEA for record keeping violations
- Can cost anywhere from $10,000 to $25,000 per violation

Criminal

- Generally occurs when the offense is so egregious or multiple deaths are attributed to the prescribing patterns

- There are no hard, fast rules for exactly what will occur in every case!!!!

- Although similar cases may be handled in much the same manner, each case is examined individually and dealt with based on the circumstances exclusive to the specific incident.

Case Study
Scenario # 1

- Dr. Jones is concerned about possible drug diversion by a patient. Dr. Jones should/could:

- Run the patient INSPECT
- Conduct random pill counts
  - Give the patient 8 only hrs to comply
  - Are all pills presented the same
  - Verify with the pharmacy

Options:

- Speak with the patient about lowering the quantity prescribed
- Change the prescribed drug possibly to an Extended Release
- Change the milligrams of the prescribed drug
- Run more routine INSPECT reports
- Educate the patient about the importance of taking the drug(s) as prescribed
- Gain compliance by the patient or consider dismissing the patient

- What if the patient is non compliant and the physician dismisses the patient due to continuing suspicions?

- The physician could report their concerns/suspicions to law enforcement.

Law Enforcement will usually:

- Run an INSPECT report:
  - If no doctor shopping patterns are revealed, the investigation is typically terminated.
  - If there are patterns/evidence of doctor shopping, the investigation will be pursued.

Case Study
Scenario # 2

- Upon beginning to utilize Urine Drug Testing as a tool to monitor treatment agreement compliance among chronic patients on opioid therapy plans, one long term, older patient tested positive for THC.
- Don't imagine this an uncommon scenario. Over the years law enforcement has received many calls from concerned physicians for this type of occurrence.
- In our society it is hard to imagine a physician dismissing a patient for testing positive for THC once.

Options

- Counsel the patient to discontinue the use of THC as it is still illegal in Indiana.
- If the patient continues usage, then possibly dismiss the patient
- Increase in opioids?
  - Question: Does this seem to be a logical treatment option? Why or why not?

Why

- It seems logical because the patient states they are still having breakthrough pain and the doctor wants to help the patient.

Why not

- High level of opioids for years
- Dependent on opioids
  - Developed a tolerance
  - Addiction
  - No improvement in functionality for 5 years
  - What other types of treatment or diagnostic should be pursued
  - Titrating doses

Consumer complaints received on Dr. Rice. Additional investigation reveals four patients have overdosed in the last year. NOW WHAT?

- Run INSPECT on Dr. Rice
- Check with DEA, ISP and MFU to determine if on-going investigation(s)
- Obtain INSPECT reports on deceased patients
- Obtain death certificates
- Obtain coroners reports
  - Levels of drugs in system
  - Polypharmacology
  - Determining death factor
  - EX: Drug- which drug?
    - Coronary disease

REMEMBER:

- At the end of the day, we are still law enforcement officers. Although we may feel these are options physicians should have looked at or followed up on, an "expert" physician's opinion must be sought. They can testify to standards of care and accepted practices.

- QUESTIONS?